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September 27, 2024

**By ECF**

Honorable Douglas E. Arpert, U.S.M.J. (Ret.)  
Three Gateway Center  
100 Mulberry Street, 15th Floor  
Newark, NJ 07102

Re: **United States ex rel. Silbersher v. Janssen Biotech Inc., et al.,  
Civil Action No. 19-12107 (MEF-CLW)**

Dear Judge Arpert:

Defendants Johnson & Johnson, Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC (collectively, “Defendants”) submit this letter in the above-captioned matter pursuant to Civil Local Rule 37.1 governing discovery disputes, the Court’s Order referring discovery disputes to the Special Master (ECF No. 331), and the Special Master’s Order regarding unresolved discovery issues (ECF No. 337).

Relator served seven expert reports on the August 7, 2024 deadline established by the Court’s scheduling order. *See* ECF 335. Since then, Relator has twice served amended versions of the report of his damages expert, Dr. Hal Singer. The most recent amendment (the “Second Amended Singer Report”) was served on August 27, 2024—twenty days after expert reports were

due.<sup>1</sup>

Relator's expert reports are improper in at least two key respects:

*First*, the Second Amended Singer Report far exceeds the proper scope of supplementation permitted by Rule 26(e). The amendments address significant new data not included in his original report and substantially alter his damages calculations by hundreds of millions of dollars.

*Second*, all seven expert reports include substantially identical statements purporting to permit the expert to testify at trial "as to any subject matter within [his] area of expertise," regardless of whether the subject matter is addressed in the report. *See infra* at 8. Any such testimony untethered from the report itself would violate the scope of supplementation permitted by Rule 26(e).

Neither deficiency may be excused as "substantially justified" or "harmless." Fed. R. Civ. P. 37(c)(1). During the meet and confer process, Defendants raised these issues with Relator and requested the withdrawal of the Second Amended Singer Report and the references to additional testimony on "any subject matter" in all the expert reports. On September 20, 2024, Relator responded that he did not plan to withdraw.

Therefore, Defendants respectfully urge the Court to strike (1) the Second Amended Singer Report; and (2) the statements in all seven expert reports purporting to permit the expert to offer additional testimony on "any subject matter" within the expert's area of expertise. Moreover, to preclude further violations of this Court's scheduling order, Defendants request that the Court enter an order requiring that Relator meet and confer with Defendants, and, if unsuccessful, seek leave of the Court before serving any new, revised, or supplemental expert reports.

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<sup>1</sup> Relator also served an amended version of the report of Dr. Robert Femia on September 25, 2024—forty-nine days after the deadline.

### LEGAL STANDARD

Federal Rule of Civil Procedure 26(a)(2)(B) provides that an expert report must contain “a *complete* statement of *all opinions* the witness will express and the basis and reasons for them.” Fed. R. Civ. P. 26(a)(2)(B) (emphases added). The purpose of this rule “is to eliminate unfair surprise to the other party.” *Amato Subaru of Am., Inc. Aquino v. Subaru of Am., Inc.*, No. CV 22-990, 2023 WL 7085095, at \*3 (D.N.J. Sept. 27, 2023) (quoting *McGuire v. Cirrus Design*, No. 07-683, 2009 WL 383541, at \*1 (E.D. Tex. Feb. 13, 2009)); see *Dunkin’ Donuts Inc. v. Patel*, 174 F. Supp. 2d 202, 211 (D.N.J. 2001). “[T]hat goal is not achieved when experts fail to provide key information in or along with their reports.” *Amato Subaru*, 2023 WL 7085095, at \*3 (quoting *McGuire*, 2009 WL 383541, at \*1).

Although Rule 26(e) requires an expert to supplement a report that is “incomplete or incorrect” “in some material respect,” Fed. R. Civ. P. 26(e)(1)(A), this rule is not a loophole that allows a party to disregard court-ordered deadlines. “Courts have repeatedly emphasized the limited scope of supplementation permitted by Rule 26(e); such supplementation is proper only for the narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report.” *Ezaki Glico Kabushiki Kaisha v. Lotte Int’l Am. Corp.*, No. CV155477MCALDW, 2019 WL 581544, at \*3 (D.N.J. Feb. 13, 2019) (quoting *Novartis Pharm. Corp. v. Actavis, Inc.*, Civ. A. No. 12-366, 2013 WL 7045056, at \*7 (D. Del. Dec. 23, 2013)).

As a result, “Rule 26(e) is not . . . a vehicle to permit a party to serve a deficient opening report and then remedy the deficiency through the expedient of a ‘supplemental’ report.” *Lidle v. Cirrus Design Corp.*, No. 08-cv-1253, 2009 WL 4907201, at \*5 (S.D.N.Y. Dec. 18, 2009). Indeed, Rule 26(e) “provides no safe harbor for [a litigant’s] lack of diligence” in serving discovery requests and gathering facts. *DAG Enters., Inc. v. Exxon Mobil Corp.*, 226 F.R.D. 95, 110 (D.D.C.

2005). In particular, the Rule does not excuse a litigant’s failure to diligently seek and obtain “readily available” data or information from its source within the Court-ordered discovery period. *Id.* at 110–11.

And Rule 26(e) does not give a litigant “the right to ignore the Court’s deadlines, reopen discovery, find ‘new facts,’ generate new expert reports, and then claim different damages.” *Id.*; *see also Ezaki Glico*, 20019 WL 581544, at \*3 (“Rule 26(e) is not an avenue to correct failures of omission because the expert did an inadequate or incomplete preparation, add new opinions, or deepen or strengthen existing opinions.” (quoting *In re Asbestos Prod. Liab. Litig. (No. VI)*, 289 F.R.D. 424, 425 (E.D. Pa. 2013))).

Rule 37(c)(1) provides that “[i]f a party fails to provide information . . . required by Rule 26(a) or (e), the party is not allowed to use that information . . . unless the failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c)(1); *accord Nicholas v. Pa. State Univ.*, 227 F.3d 133, 148 (3d Cir. 2000).

## ARGUMENT

### **I. The Court Should Strike the Second Amended Singer Report.**

The Second Amended Singer Report is untimely. The deadline for Relator to serve his expert reports was August 7, 2024. *See* ECF 335. Relator served Dr. Singer’s original report on that date, but has twice served amended versions.

The First Amended Singer Report, served on August 9, 2024, corrected multiple calculation errors in the original report, and consequently altered Dr. Singer’s damages estimate by more than \$400 million. The original report calculated an “Aggregate Damages range” from \$980 million to \$2.39 billion. Exh. A, Original Singer Report ¶¶ 5, 78–94 (dated Aug. 7, 2024). By contrast, the First Amended Report reduced the lower bound of the “Aggregate Damages range” by \$430 million (from \$980 million to \$550 million), and also substantially altered many

of Singer’s damages “Scenario” estimates within “Aggregate Damages range.” Exh. B, First Amended Singer Report ¶¶ 78–94 (Aug. 9, 2024).<sup>2</sup>

The Second Amended Singer Report was served 20 days after the deadline, on August 27, 2024. Exh. C, Second Amended Singer Report (Aug. 27, 2024). As its opening paragraph explains, the Second Amended Singer Report different from the prior reports in key respects. In particular, the new report:

- analyzes historical claims data produced to Relator by the Centers for Medicare & Medicaid Services (CMS) on August 13, 2024;
- “corrected erroneous citations and certain word choices”; and
- “recalculated” Singer’s analysis of purported overcharges of Medicare and the Veterans Health Administration reflected in Table 6 of the Report.

*Id.* ¶ 1.

As a result of these changes, the Second Amended Singer Report significantly modifies the “Aggregate Damages range,” increasing the lower bound by \$50 million (from \$550 million to \$600 million), and increasing the upper bound by \$160 million (from \$2.39 billion to \$2.55 billion). *Compare id.* ¶¶ 6, 79–95, with Exh. B, First Amended Singer Report ¶¶ 5, 78–94.

Further, the new report previews that yet *another* amendment—a *Third* Amended Singer Report—may be served in the future if Relator obtains additional data from Medicaid that was not received at the time of the reports submitted to date. Exh. C ¶ 2.

The Second Amended Singer Report was served long after the Court-imposed deadline. Therefore, Relator may rely upon it only if it is a proper supplement within the bounds of Rule 26(e). *See* Fed. R. Civ. P. 37(c)(1) (a “party is not allowed to use . . . information” that it “fails to provide . . . as required by Rule 26(a) or (e)”). It is not.

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<sup>2</sup> The First Amended Singer Report also corrected several typos and formatting issues, including an error in Singer’s middle initial.

The Second Amended Singer Report exceeds the “limited scope of supplementation permitted by Rule 26(e).” *Ezaki Glico*, 2019 WL 581544, at \*3. This new report analyzes an entirely new set of “Medicare Prescription Drug Event (PDE) data” from CMS, which “includes drug utilization information for the abiraterone acetate authorized generic” sold by a subsidiary of Defendants. Exh. C at ¶ 1. None of this data was included or analyzed in the original report served on the deadline. Rule 26(e) does not permit Singer to “add new opinions” by incorporating new data into his report. *Ezaki Glico*, 2019 WL 581544, at \*3 (quoting *In re Asbestos Prods.*, 289 F.R.D. at 425).

It is no excuse that Singer purports to have received the data from CMS after the Court-imposed deadline for the submission of his expert report. *See* Exh. C ¶ 1 (stating that CMS produced the data on August 13, 2024). Any delay was caused wholly by Relator’s lack of diligence in pursuing discovery in this action.

As the Court is aware, Relator filed his complaint more than five years ago, discovery has been open for more than three years, and Relator twice obtained substantial extensions of the fact discovery period before it concluded on June 7, 2024. *See* ECF 325; ECF 335.

The historical CMS claims data Relator added to the Second Amended Singer Report was “readily available” to him throughout the discovery period. *DAG Enters., Inc. v. Exxon Mobil Corp.*, 226 F.R.D. at 110-11. Rule 26(e) does not excuse Relator’s failure to diligently seek and obtain this data from CMS in time to meet the expert-report deadline. *Id.* at 110–11.

Nor can Relator claim that he could not have “foreseen” his need to obtain this data sooner. *Id.* Relator’s allegation that Defendants submitted false claims to government healthcare programs, including Medicare and Medicaid, is at the heart of his Complaint. *See, e.g.*, ECF 63, Second Am. Compl. ¶ 18. Thus, Relator has undoubtedly known from the outset of this litigation

that alleged damages to these government healthcare programs would be a necessary element of his proof. Yet, Relator failed to serve a subpoena on CMS for *nearly two years* after fact discovery opened. *See* ECF 317, Relator’s Proposed Order Regarding Issuance of Subpoena (Jan 29, 2024).<sup>3</sup> Had Relator exercised reasonable diligence when conducting fact discovery, he would have served his subpoena on CMS far earlier, with adequate time to receive the information and include it in his expert reports prior to the deadline. Instead, Relator waited until the last minute and, when he did not obtain the information before the deadline, had his expert file an incomplete report. Rule 26(e), however, does not permit a party to serve amended expert reports correcting “omission[s]” that are attributable to “inadequate or incomplete preparation.” *Ezaki Glico*, 2019 WL 581544, at \*3; *accord Lidle*, 2009 WL 4907201, at \*5. That is plainly the cause of the deficiencies in Singer’s reports here. Relator could have and should have sought and obtained this information from CMS sooner if he wished to include it in an expert report.

Even more glaringly, now nearly two months after expert reports were due, Relator indicates that he believes that Singer’s analysis *still* is not complete. As noted, the Second Amended Singer Report states that he may file yet *another* amended version, if and when CMS produces additional Medicaid data in response to Relator’s belated subpoena. *Supra* at 5. This reservation is particularly perplexing because Defendants already produced Medicaid rebate and fee data for Zytiga to Relator well over a year ago, in June 2023. Put simply, Singer’s failure to account for Medicaid claims in his three expert reports lacks any justification.

Singer’s initial Report makes clear that Relator understood the report was incomplete at

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<sup>3</sup> Despite indicating to the Court in a November 13, 2023 status letter that CMS had requested that the Court issue the relevant subpoenas, ECF 293 at 12–13, Relator delayed nearly three additional months, until shortly before the then-in-place fact discovery deadline to submit the subpoenas to the Court for issuance, ECF 317.

the time of the court-imposed deadline. Yet rather than ask the Court to modify the scheduling order, Relator knowingly chose to violate its deadlines and improperly cut into the period reserved for Defendants' expert discovery.

These amendments substantially prejudice Defendants and cannot be excused as "substantially justified" or "harmless." Fed. R. Civ. P. 37(c)(1). The Court-approved scheduling order makes Defendants rebuttal expert reports due on December 9, 2024. *See* ECF 335. As Defendants explained to Relator and the Court in negotiating that schedule, Defendants will need the entirety of that period to adequately prepare their rebuttals. Indeed, while this case has been open for over five years, due to the nature of the claims, fact discovery was substantially one-sided, with Relator taking the vast majority of it. Throughout that period, Relator shifted his theory of the case in multiple significant ways. *See* ECF 354, Defendants' Opposition to Relator's Privilege Motion. Defendants' receipt of his numerous expert reports on August 7 was the first time Relator was required to articulate his theory of the case in meaningful detail beyond the complaint, and Defendants' first opportunity properly to analyze and respond to it.

On the critical issue of damages, however, Relator has now deprived Defendants of 20 days of their response period—by serving the Second Amended Singer Report 20 days late—and purports to reserve the right to further prejudice Defendants by serving yet another amendment on some uncertain future date.

Rule 26(e) does not permit this gamesmanship and the Court should strike the Second Amended Singer Report.

**II. The Court Should Strike the Statements in All Seven of Relator's Expert Reports Stating That the Experts May Testify Further as to "Any Subject Matter" Within Their Expertise.**

The Court should also strike certain statements in all seven of Relator's expert reports. As Relator has already demonstrated through the amended versions of Singer's report, Relator has no



hesitation in offering new expert opinions well after the Court-imposed deadline of August 7, 2024. And each of Relator's experts threatens to offer new opinions in violation of Rule 26(e) well after that deadline has passed. Six of these reports contain an identical statement in which the expert asserts that he may testify further as to "any subject matter" within his "area of expertise":

"I may testify further as to **any subject matter within my area of expertise** that may be useful to inform the Court or trier of fact as to the bases for my opinions. I may also testify concerning additional subject matter properly raised at trial that is within my area of expertise. In addition, I may testify as to any subject matter responsive or in rebuttal to contentions advanced at trial by Defendants."<sup>4</sup>

The seventh report (from Dr. Mark J. Ratain) contains a substantially similar statement, with the addition of one extra clause at the end of the first sentence:

"I may testify further as to any subject matter within my area of expertise that may be useful to inform the Court or trier of fact as to the bases for my opinions, or otherwise assist the Court or a trier of fact to understand the evidence or determine factual issues. I may also testify concerning additional subject matter properly raised at trial that is within my area of expertise. In addition, I may testify as to any subject matter responsive or in rebuttal to contentions advanced at trial by Defendants."<sup>5</sup>

Each of these experts' statements that they "may testify further as to any subject matter within [their] area of expertise" indicates an intent to improperly supplement their report and offer new opinions in violation of Rule 26(e). Relator has no right to do so and his experts' reservation of such a right is wholly unjustified.

Rule 26(a)(2)(B) requires that an expert report must contain "a *complete* statement of *all opinions* the witness will express." Fed. R. Civ. P. 26(a)(2)(B) (emphases added). Although an

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<sup>4</sup> Exh. B, First Amended Singer Report ¶ 94 n.168 (emphasis added); Exh. C, Second Amended Singer Report ¶ 95; Exh. D, Bahr Report ¶ 213; Clark Report at 92; Amended Femia Report at 21–22; Hyman Report at 53; Tu Report ¶ 285.

<sup>5</sup> Exh. D, Ratain Report ¶ 65.

expert may file a supplemental opinion “for the narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report,” the expert may not “add *new opinions*” that were not part of the original expert report. *Ezaki Glico*, 2019 WL 581544, at \*3 (emphasis added).

But each of these seven experts purports to reserve the right to do precisely that. Permitting an expert to testify as to “*any subject matter*” within his area of expertise—including subjects that were *not* addressed in the expert’s original report—would improperly invite entirely new opinions from the expert, in violation of Rule 26(e). The law is unambiguous that Rule 26(e) “supplementation is proper only for the narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report.” *Id.* New opinions on new “subject matter” is not permitted, and would defeat the purpose of Rule 26(a)(2)—“eliminat[ing] unfair surprise” and prejudice to the other party—by allowing Relator to spring new expert opinions on Defendants, either later in discovery or at trial, that are untethered from the expert opinions actually set forth in the experts’ reports. *Amato Subaru*, 2023 WL 7085095, at \*3.

These deficiencies in the expert reports are not “substantially justified” or “harmless.” Fed. R. Civ. P. 37(c)(1). Defendants would undoubtedly be prejudiced by the “unfair surprise” of additional testimony that goes beyond the opinions in the original expert report. *Amato Subaru*, 2023 WL 7085095, at \*3. Moreover, even if Relator’s experts do not offer any testimony on new topics in future discovery or at trial, Defendants should not be required to face the uncertainty that the experts’ purported reservation to do so creates. In addition, if Relator’s experts offer such opinions in the future, it will require further litigation on an expert-by-expert basis and unnecessarily distract the parties and the Court and detract from their time and resources, especially if the issue arises during trial. The rule is unequivocal: Relator’s experts cannot offer

new opinions that do not appear in their reports. In contrast, Relator suffers no harm should his experts' "reservations of rights" be stricken. If Relator believes it necessary to supplement his expert reports consistent with Rule 26, he may raise that issue with the Court at the appropriate time. Defendants should not bear the burden of keeping improper and untimely opinion testimony out; rather, Relator should bear the burden of bringing such testimony in. Therefore, the Court should strike these statement now.

### **CONCLUSION**

For the foregoing reasons, the Court should (1) strike the Second Amended Singer Report served by Relator on August 27, 2024, (2) strike the statements in each of Relator's seven expert reports asserting that the experts may testify further as to "any subject matter within [their] expertise,"<sup>6</sup> and (3) enter an order requiring that Relator meet and confer with Defendants, and, if necessary, seek leave of the Court prior to serving any new, revised, or supplemental expert report.

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<sup>6</sup> Exh. B, First Amended Singer Report ¶ 94 n.168; Exh. C, Second Amended Singer Report ¶ 95; Exh. D, Bahr Report ¶ 213; Clark Report at 92; Amended Femia Report at 21–22; Hyman Report at 53; Ratain Report ¶ 65; Tu Report ¶ 285.

September 27, 2024

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